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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,473	07/07/2006	David Mark Allison	G40.2-13290-US01	5905

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EXAMINER

SCHAPER, MICHAEL T

ART UNIT	PAPER NUMBER
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3775

MAIL DATE	DELIVERY MODE
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02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,473	Applicant(s) ALLISON, DAVID MARK	
	Examiner MICHAEL SCHAPER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-7-06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: washer 124 (page 8, line 20) and washer 224 (page 8, line 20). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because the first sentence of the abstract is not a complete sentence. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

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on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claims 3-5, 10-14, and 16 are objected to because of the following informalities:

In claim 3, line 3, "**centre**" should read "center";

In claim 10, line 12, "**portions**" should read "portion"; and

In claim 16, lines 5-6, "**pair overlapped**" should read "pair of overlapped".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite part of the human body in combination with the device, namely the following claim limitations: "**each fixing portion if fixed to one or more of the bone pieces by the fasteners**" (claim 1, lines 12-13) and "**connecting members extend across one or more fissures between the bone pieces**" (claim 1, lines 14-15). It has been held that a claim directed to or

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including within its scope, a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of limited, but exclusive property right in a human being is prohibited by the constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). For examination purposes, all claims will be considered as if such limitations involving the combination with a human were not present.

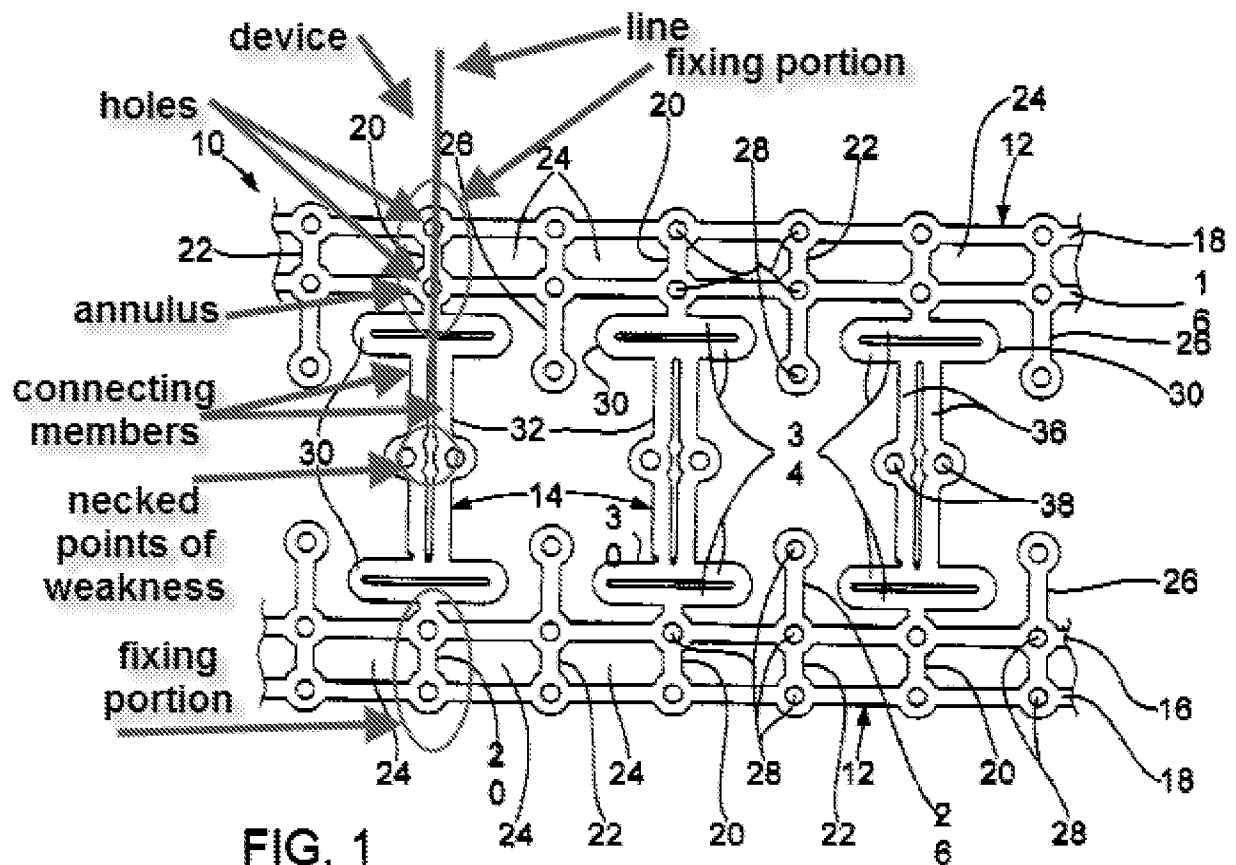
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Murray (US 6093188).

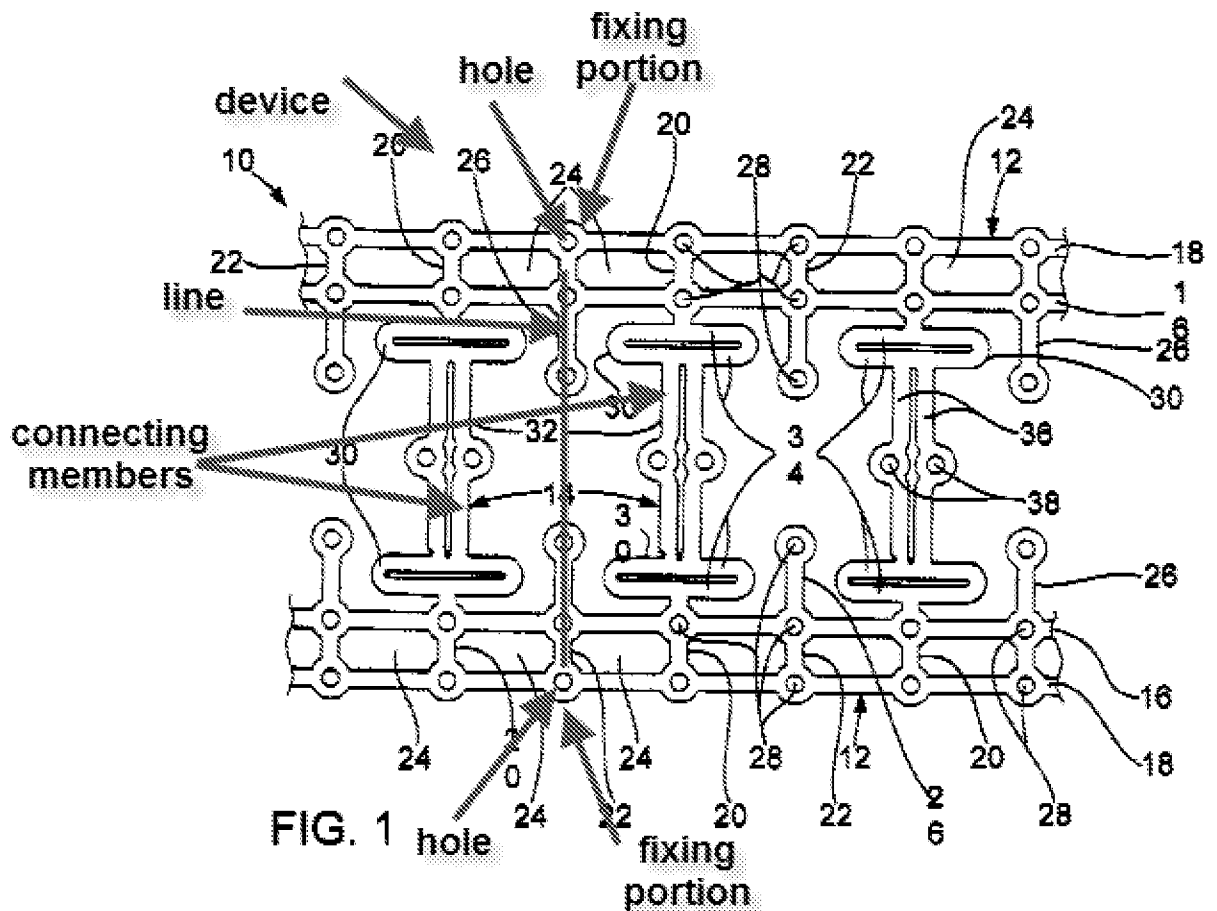


The claimed phrase “**the connecting members are simultaneously deformed such that the fissures are closed with the bone pieces held in compression**” (claim 1, lines 15-17) is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

As to claims 1-4 and 6-9, Murray discloses (see FIGURE inserted above) a bone fixing device for fixing bone pieces together, the bone fixing device comprising a pair of spaced-apart fixing portions (see above), each having at least one hole (see above)

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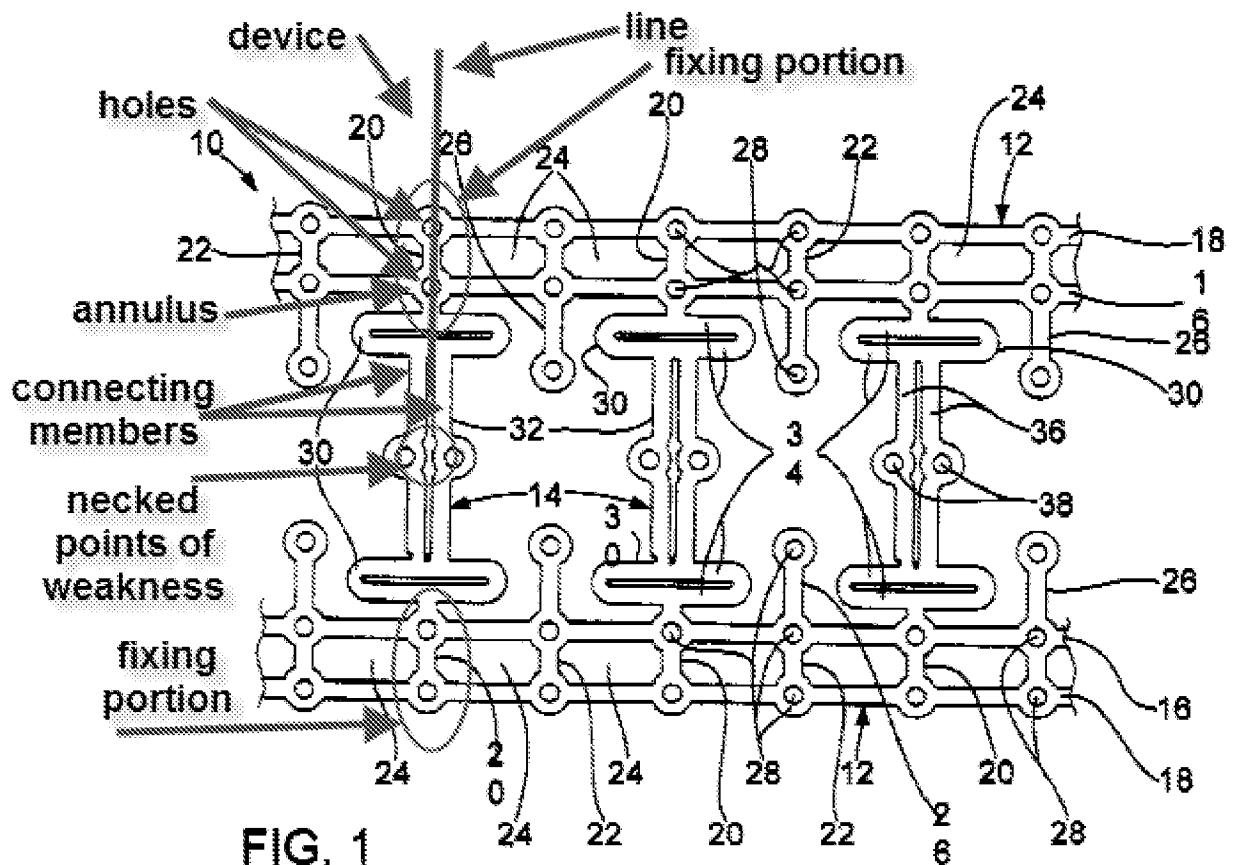
dimensioned such that a fastener capable of extending therethrough; and, a pair of substantially rigid connecting members (see above) extending between the fixing portions, the connecting members being deformable without substantially losing rigidity (col. 2 / line 66 to col. 3 / line 5), whereby, in use, each fixing portion is fixable to one or more of the bone pieces by the fasteners such that the connecting members extend across one or more fissures between the bone pieces (see FIG. 3), and the connecting members are capable of being simultaneously deformed such that the fissures are closed with the bone pieces held in compression (see FIG. 4); wherein each fixing portion comprises an annulus (see above); wherein the connecting members are deformable symmetrically with respect to a line (see above) extending through the centre of the pair of fixing portions such that the fixing portions are drawn toward one another along the line; wherein to achieve the symmetrical bending the connecting members are bent apart (see FIGS. 1-2); wherein the connecting members are initially parallel (see above); wherein each connecting member has at least one point of weakness at which bending of the connecting member occurs in preference to elsewhere on the connecting member (see above); wherein each of the at least one point of weakness is a necked portion of the respective connecting member (see above); wherein at least one of the fixing portions comprises at least two holes each for receiving a fastener (see above).



As to claims 1, 3, and 5, Murray discloses (see FIGURE inserted above) a bone fixing device for fixing bone pieces together, the bone fixing device comprising a pair of spaced-apart fixing portions (see above), each having at least one hole (see above) dimensioned such that a fastener capable of extending therethrough; and, a pair of substantially rigid connecting members (see above) extending between the fixing portions, the connecting members being deformable without substantially losing rigidity (col. 2 / line 66 to col. 3 / line 5), whereby, in use, each fixing portion is fixable to one or more of the bone pieces by the fasteners such that the connecting members extend across one or more fissures between the bone pieces (see FIG. 3), and the connecting

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members are capable of being simultaneously deformed such that the fissures are closed with the bone pieces held in compression (see FIG. 4); wherein the connecting members are deformable symmetrically with respect to a line (see above) extending through the centre of the pair of fixing portions such that the fixing portions are drawn toward one another along the line; wherein to achieve the symmetrical bending the connecting members are pinched together (see FIGS. 1-2).



As to claims 15 and 17, Murray discloses a method of fixing bone pieces separated by a fissure, comprising the steps of providing at least one bone fixing device (see FIGURE inserted above) having a pair of spaced-apart fixing portions (see above) each having at least one hole (see above) and in the form of an annulus (see above) being

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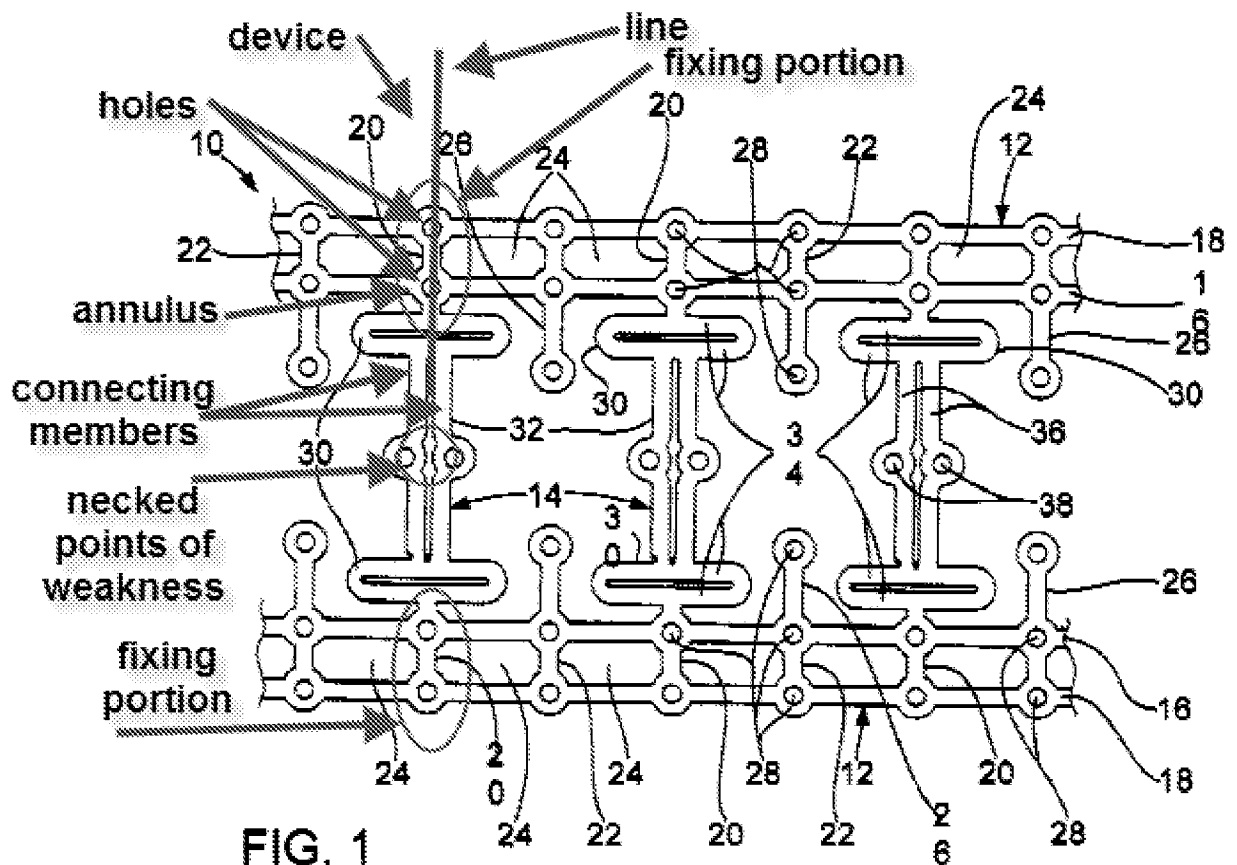
dimensioned such that a fastener can extend therethrough and a pair of deformable connecting members (see above) extending between the fixing portions (see FIG. 1); fixing one of the fixing portions to one bone piece using a fastener and the other fixing portion to another bone piece using another fastener such that the connecting members extend across the fissure (col. 3 / lines 31-34); and, simultaneously deforming the connecting members such that the fixing portions are drawn together (col. 4 / lines 6-17); wherein simultaneously deforming the connecting members in the deforming step further comprises substantially symmetrically deforming the connecting members (see FIG. 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6093188) in view of Michelson (US 2003/0060828).



As to claims 10-11, Murray discloses a bone fixing device (see FIGURE inserted above), the bone fixing device comprising a pair of spaced-apart fixing portions (see above), each having at least one hole (see above) dimensioned such that a fastener capable of extending therethrough; and, a pair of substantially rigid connecting members (see above) extending between the fixing portions, the connecting members being deformable without substantially losing rigidity (col. 2 / line 66 to col. 3 / line 5); wherein the fixing portion is in the form of an annulus (see above).

Murray discloses the claimed invention except for a system comprising at least two bone fixing devices, whereby, in use, at least one of the fixing portions of each bone fixing device can be concentrically overlapped with a fixing portion of another bone

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fixing device such that a fastener can extend through the holes of the overlapped fixing portions.

Michelson discloses a system comprising at least two bone fixing devices, whereby, in use, at least one of the fixing portions of each bone fixing device can be concentrically overlapped with a fixing portion of another bone fixing device such that a fastener can extend through the holes of the overlapped fixing portions (FIG. 1, [0074]) for covering of a range of sizes of necessary plated surfaces.

At the time of invention, it would have been obvious to a person of ordinary skill in the art to have modified Murray with a system comprising at least two bone fixing devices, whereby, in use, at least one of the fixing portions of each bone fixing device can be concentrically overlapped with a fixing portion of another bone fixing device such that a fastener can extend through the holes of the overlapped fixing portions in view of Michelson for covering of a range of sizes of necessary plated surfaces.

As to claim 16, Murray discloses the claimed invention except for a method further comprising the providing step involving overlapping an annulus of a first bone fixing device with an annulus of a second bone fixing device such that a fastening means can extend through both of a pair of overlapped annuli.

Michelson discloses a method further comprising the providing step involving overlapping an annulus of a first bone fixing device with an annulus of a second bone fixing device such that a fastening means can extend through both of a pair of overlapped annuli (FIG. 1, [0074]) for covering of a range of sizes of necessary plated surfaces.

At the time of invention, it would have been obvious to a person of ordinary skill in the art to have modified Murray with a method further comprising the providing step involving overlapping an annulus of a first bone fixing device with an annulus of a second bone fixing device such that a fastening means can extend through both of a pair of overlapped annuli in view of Michelson for covering of a range of sizes of necessary plated surfaces.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6093188) in view of Michelson (US 2003/0060828) further in view of Farris et al. (US 6669700).

Murray in view of Michelson disclose the claimed invention except for a system further comprising at least one washer for overlapping with an annulus of a bone device, the washer having a hole that is frusto-conical or cylindrical in shape to receive the head of a bone screw.

Farris discloses a system comprising a washer capable of overlapping with an annulus of a bone device, the washer (90) having a hole that is frusto-conical (94) and cylindrical (93) in shape to receive the head and shaft, respectively, of a screw (see FIGS. 15-16) for the complementary mating of a screw to a plate.

At the time of invention, it would have been obvious to a person of ordinary skill in the art to have modified Murray in view of Michelson with a system comprising a washer capable of overlapping with an annulus of a bone device, the washer having a hole that is frusto-conical and cylindrical in shape to receive the head and shaft,

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respectively, of a screw in view of Farris for the complementary mating of a screw to a plate.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL SCHAPER whose telephone number is (571)270-7413. The examiner can normally be reached on M-F, 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. S./
Examiner, Art Unit 3775

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732